K010349

Catheter Innovations®

FEB 2 8 2001

PASV® Pressure Activated Safety Valve

January 23, 2001

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD – 20850 – USA.

SPECIAL PREMARKET NOTIFICATION [510(k)] SUMMARY

Submitter's name, address, phone and fax numbers:

SUBMITTER: Catheter Innovations, Inc.
3598 West 1820 South
Salt Lake City, Utah – 84104

TELEPHONE: (801) 954-8444

FAX: (801) 954-8484

ESTABLISHMENT REGISTRATION NUMBER: 1723743

OWNER OPERATOR NUMBER: 9025151

Contact person: Roger L. Richins
Vice President of Technology and Regulatory Affairs

Date summary prepared: January 26, 2001

Name of the device: Dual Lumen Midline Catheter

Classification: 880.5200 Intravascular Catheter, Class II, (Performance Standards)

Legally marketed device to which equivalent:

PREDICATE DEVICE #1: Catheter Innovations Single Lumen Midline Catheter
510(k) Number: K963215 November 14, 1996
Title: Clampless Valved Midline Catheter (CV-MLC)

PREDICATE DEVICE #2: Catheter Innovations Single Lumen PICC Catheter
510(k) Number: K963097 October 18, 1996
Title: Clampless Valved Catheter – PICC (CVC-PICC)

PREDICATE DEVICE #3: Catheter Innovations Dual-Lumen PICC Catheter.
510(k) Number: K981368 May 1, 1998
Title: PASV™ Dual Lumen Peripherally Inserted Central Catheter (PICC)

CATHETER INNOVATIONS, INC
3598 WEST 1820 SOUTH
SALT LAKE CITY, UTAH 84104-4959
801.954.8444 800.418.2828 FAX 801.954.8484

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Purpose of this premarket notification: Catheter Innovations desires to add to the four sizes of single lumen midline catheters, (already approved K963215), two sizes of dual lumen midline catheters. This premarket notification describes these additional catheters and their relationship to the single lumen variety.

Description of the device:

The Catheter Innovations, Inc., PASV® Dual-Lumen Midline Catheter with integral PASV® protection is constructed of specially formulated and processed silicone rubber. The catheter is radiopaque with a female luer lock hub. The catheter features a molded, soft silicone suture wing with an extension tube. A peel away sheath introducer allows for percutaneous insertion. A stylet guide/flush assembly with locking device is provided for use during the insertion procedure. A wire stylet is provided to stiffen the catheter for advancement into the vein.

The patented PASV® valve located within the female luer lock hub is a unique safety feature of the catheter. The valve remains closed when the catheter is not in use and when subjected to normal venous pressures. When positive fluid pressure is applied through the luer lock hub, the valve opens allowing infusion of fluids through the catheter. When negative pressure (aspiration) is applied, the valve opens allowing for withdrawal of blood into a syringe.

As a precaution against contamination, a sterile end cap is placed on the female luer lock hub when the catheter is not in use.

This product is to be inserted, used, maintained and removed in accordance with institutional and/or Centers for Disease Control (CDC) guidelines or policies.

Each catheter is provided in a sterile package for single use.

Dual-Lumen Midline Catheter – size variations:

DESCRIPTION	DUAL-LUMEN 5 FRENCH	DUAL-LUMEN 6 FRENCH
Identification number	MLC502IK	MLC 602IK

Intended use of the proposed device:

The PASV® MLC is indicated for use in establishing peripheral access for administration of fluids including, but not limited to, hydration agents, antibiotics, analgesics, and blood products. It is also indicated for blood specimen withdrawal.

This product is effective for peripheral venous access in adults, children and infants who require intravenous therapy.

Summary of the technological characteristics of our device and its equivalency compared to the predicate device:

Compared to Catheter Innovations' single lumen Midline catheter, this product and its package are exactly the same in design, materials, description, intended use and instructions for use. The only difference is that there are two lumen available for use, instead of one. (See examples included with this application).

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Compared to Catheter Innovations approved dual-lumen PICC catheters, this Midline product is exactly the same in design, materials and description except that it is shorter and its use in the body is in the peripheral circulatory system. The PICC catheter is used in the central circulatory system (near the heart).

Conclusions: The Catheter Innovations Dual-Lumen Midline Catheter is substantially equivalent to the products identified herein and currently being marketed under approved 510(k) Premarket Notifications.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Roger L. Richins
Vice President of Technology and Regulatory Affairs
Catheter Innovations, Incorporated
3598 West 1820 South
Salt Lake City, Utah 84104-4859

Re: K010349
Trade Name: Dual Lumen Midline Catheter
Regulatory Class: II
Product Code: LJS
Dated: February 2, 2001
Received: February 5, 2001

Dear Mr. Richins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: PASV® Dual-Lumen Midline Catheter

Indications for Use:

The PASV® MLC is indicated for use in establishing peripheral access for administration of fluids including, but not limited to, hydration agents, antibiotics, analgesics, and blood products. It is also indicated for blood specimen withdrawal.

This product is effective for peripheral venous access in adults, children and infants who require intravenous therapy.

Warning: The PASV® MLC is NOT indicated for infusion of the following:

- Hypertonic nutrition solutions with finsl glucose concentrations greater than 10%.
- Continuously infused vesicant drugs.
- Any medication contraindicated for infusion into the peripheral system.

Catheter Innovations, Inc., PASV® Dual-Lumen Midline Catheters have the same intended use as our Single-Lumen Midline Catheters (K~~963097~~ 963915).

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON OTHER PAVE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010349

Prescription Use ✓ **OR** **Over-the-Counter Use** _____

(Optional Format 1-2-96)